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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/755,456	01/05/2001	Frederic Delbac	1566-00	5009

7590

09/19/2002

IP Department
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36th Floor
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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 09/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/755,456

Applicant(s)
Delbac et al

Examiner
Mark Navarro

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1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above, claim(s) 3 and 6-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 33, and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-12, and the 55 kD protein represented by SEQ ID NO: 1 in Paper No. 9, received July 1, 2002 is acknowledged. The traversal is on the ground(s) that Group II, including claim 13, depends upon Group I and that both groups are classified in the same class 530. This is not found persuasive because group I is drawn to proteins, while Group II is drawn to antibodies. Each of these groups represent biological molecules with different functions and structural characteristics. Furthermore, each group is classified in a different subclass, thereby necessitating a separate search of each of the biological molecules in different areas. Applicant's further strenuously traverse the requirement for a single sequence. However as set forth in MPEP 803.04, biological molecules with different sequences are separate inventions. Consequently, the requirement for restriction to a single sequence is maintained.

Upon further reconsideration, Group VII, drawn to pharmaceutical compositions has been rejoined with the elected Group I.

Consequently claims 1-34 are pending in the instant application, of which claims 3, and 6-32 are withdrawn from further consideration as being drawn to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

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SEQUENCE LISTING

2. Applicants attention is drawn to the specification, pages 17, 20 and 21, which recite multiple amino acid sequences. To fully comply with the sequence requirements applicant is required to give a sequence identification tag to all amino acid sequences of at least 4 amino acids or 10 or greater nucleotides. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Claims 33-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions comprising the purified microsporidian polar tube protein, does not reasonably provide enablement for pharmaceutical/vaccine compositions comprising the purified microsporidian polar tube protein, or pharmaceutical/vaccine compositions comprising a fragment of the polar tube protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification provides insufficient guidance of how to use the claimed polypeptides as a vaccine. It is well recognized in the art that it is unclear whether a single protein derived from a pathogen will elicit protective immunity. Ellis, R.W. (see Chapter 29 of "VACCINES" [Plotkin, S.A *et al.*, (ed.), published by W.B. Saunders Company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem

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(of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies ...and thus protect the host against attack by the pathogen."

A vaccine "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Since no working examples are set forth in the specification that the claimed polypeptides are useful for vaccination and the art teaches of the unpredictability of using a single antigen for vaccination it would be an undue burden and be unpredictable to use the broadly claimed product for vaccination.

4. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of "functionally equivalent derivative thereof." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, at what level of functioning are the molecules deemed to be equivalent, 99%, 90%, 50%, etc? Furthermore, what function is being measured, e.g., antigenicity, immunogenicity, enzymatic activity? Without a clear definition as to the metes and

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bounds of the term “functionally equivalent derivative thereof” one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. *Claims 1, 4, and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Keohane et al.*

The claims are directed to purified microsporidian polar tube proteins.

Keohane *et al* (Molecular and Biochemical Parasitology Vol. 79, pp 225-259, 1996) (IDS ref AS) disclose of the purification and characterization of a microsporidian polar tube protein. Keohane *et al* further determined the molecular weight of the protein as well as diluting the protein in 50 mM Tris for subcutaneous immunization. (See pages 255-257).

It is noted that Keohane *et al* do not disclose of the sequence of the purified microsporidian polar tube protein, however since both the instantly claimed protein as well as the

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protein characterized by Keohane *et al* are microsporidian polar tube proteins, the protein disclosed by Keohane *et al* is deemed to be a functionally equivalent derivative thereof.

6. Claims 1-2, 4-5, and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Delbac *et al*.

The claims are directed to purified microsporidian polar tube proteins.

Delbac *et al* (Journal of Eukaryotic Microbiology Vol 44, No. 6, page 77S, 1997) (IDS ref AR) disclose of the purification of a 55 kDa polar tube protein from the microsporidian species, *Encephalitozoon cuniculi*. Delbac *et al* further set forth of determining the isoelectric point to be about 5. Delbac *et al* further set forth of expressing the protein in *E. coli* and injecting the protein in mice. (See entire article).

In view that the instantly filed application claims a microsporidian polar tube protein obtained from *Encephalitozoon cuniculi* with a molecular weight of 55 kDa and an isoelectric point of about 5, and that Delbac *et al* set forth of a microsporidian polar tube protein obtained from *Encephalitozoon cuniculi* with a molecular weight of 55 kDa and an isoelectric point of about 5, the disclosure of Delbac *et al* is deemed to anticipate the claimed invention.

It is noted that Delbac *et al* do not characterize the sequence of the isolated protein, however, in view that both the instantly claimed protein and the protein disclosed by Delbac *et al* are:

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--obtained from *Encephalitozoon cuniculi*
are polar tube proteins
have a molecular weight of 55 kDa
and an isoelectric point of about 5

the sequence of the protein is deemed to inherently be that of SEQ ID NO: 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

September 17, 2002